

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 7 HEALTH CLINICS

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ATTACHMENTS

42 CFR 416.1 TO 416.200
(Ambulatory Surgical Centers)

and

42 CFR 405.2100 to 405.2163
(Hemodialysis Services)

10-1-05 Edition of the
Code of Federal Regulations

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 7 HEALTH CLINICS

7-001 SCOPE AND AUTHORITY: These regulations govern licensure of Health Clinics. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-462.

7-001.01 These regulations apply to any health care facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at such facility. Health clinic includes, but is not limited to:

1. An ambulatory surgical center;
2. A public health clinic;
3. A facility where 10 or more abortions as defined in Neb. Rev. Stat. § 28-326 are performed during any one calendar week;
4. A facility providing hemodialysis and not licensed as another type of health care facility; or
5. A facility providing labor and delivery services and not licensed as another type of health care facility.

7-001.02 Health clinic does not include:

1. A health care practitioner facility which is a residence, office or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing Law or any distinct part of such residence, office or clinic unless such facility:
 - a. Is an ambulatory surgical center;
 - b. Performs 10 or more abortions during any one calendar week;
 - c. Provides hemodialysis services; or
 - d. Provides labor and delivery services.
2. A facility which provides only routine health screenings, health education or immunizations.

7-002 DEFINITIONS

Abuse means any knowing, intentional or negligent act or omission on the part of a person which results in physical, sexual, verbal or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment and services to a patient.

Activities of daily living (See definition of "Care.")

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer for a health clinic and may include such titles as administrator, chief executive officer, manager, superintendent, director or similar designation.

Ambulatory surgical center means a facility:

1. Where surgical services are provide to persons not requiring hospitalization who are admitted to and discharged from such facility within the same working day and are not permitted to stay overnight at such facility;
2. Which meets all applicable requirements for licensure as a health clinic under the Health Care Facility Licensure Act; and
3. Which has qualified for a written agreement with the Health Care Financing Administration of the United States Department of Health and Human Services or its successor to participate in Medicare as an ambulatory surgical center as defined in 42 CFR 416.1 to 416.200 or which receives other third-party reimbursement for such services.

Ambulatory surgical center does not include an office or clinic used solely by a practitioner or group of practitioners in the practice of medicine, dentistry, or podiatry.

Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

Biological means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact direction, which do not require alteration of the

standard procedure, and for which the results and patient responses are predictable; and

3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Complaint means an expression of a concern or dissatisfaction.

Completed application means the application that contains all the information specified in 175 NAC 7-003 and includes all required attachments and documentation and the licensure fee.

Department means the Department of Health and Human Services Regulation and Licensure.

Designee means a person who is authorized by law or the patient to act on his or her behalf, for example a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Existing facility means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 7.

Exploitation means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, or extortion or by any unlawful means.

Facility means a health clinic as defined.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Food service means the storage, preparation, serving, and disposition of food intended for consumption in a health clinic. Food service does not include provision of prepackaged snacks or nutritional supplements.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, a psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility or a substance abuse treatment center.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Health care practitioner facility means the residence, office, or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing law or any distinct part of the residence, office, or clinic.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of "Care.")

Health clinic means a facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at such facility. Health clinic includes, but is not limited to, an ambulatory surgical center or a public health clinic.

Health clinic does not include:

1. A health care practitioner facility
 - a. Unless such facility is an ambulatory surgical center;
 - b. Unless ten or more abortions, as defined in subdivision (1) of Neb. Rev. Stat. § 28-326, are performed during any one calendar week at such facility; or

- c. Unless hemodialysis or labor and delivery services are provided at such facility; or
2. A facility which provides only routine health screenings, health education, or immunizations.

Hemodialysis means the mechanical process of removing unwanted wastes and fluid from the blood to prevent toxic buildup in patients whose kidneys no longer perform this function. This is done by circulating a patient's blood through a semipermeable membrane, or dialyzer. Circulation occurs outside the patient's body.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication provision means the component of the administration of medication that includes giving or applying a dose of a medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment, deprivation or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment or services necessary to avoid physical harm or mental anguish of a patient.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 7.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category which now intend to seek licensure in a different category.

Patient means a person who receives care and treatment as recommended by a medical practitioner at a health clinic.

Personal care (See definition of "Care.")

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physician means any person authorized to practice medicine in this state as provided in Neb. Rev. Stat. §§ 71-102 to 71-110.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme in which a medication is not routine, is taken as needed and requires assessment for need and effectiveness.

Public health clinic means the department, and county, city-county, or multicounty health department, or any private not-for-profit family planning clinic licensed as a health clinic.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections or particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Routine health screenings means the collection of health data through the administration of a screening tool designed for a specific health problem, evaluation, and comparison of results to referral criteria, and referral to appropriate sources of care, if indicated.

Schematic plans means a diagram of the facility or service which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Screening tool means a simple interview or testing procedure to collect basic information on health status.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to patients. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to patients or within their hearing distance.

7-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a health clinic must first obtain a license from the Department. A facility must not hold itself out as a health clinic or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the health clinic meets the care, treatment, operational and physical plant standards contained in 175 NAC 7.

7-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 7-006 and 7-007. The application is not complete until the Department receives documents specified in 175 NAC 7-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the health clinic. The Department determines whether or not the applicant for an initial license meets the standards contained in 175 NAC 7 and the Health Care Facility Licensure Act.

7-003.01A Applicant Responsibilities: An applicant for an initial health clinic license must:

1. Intend to provide health clinic services as defined;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 7-007;
3. Submit a written application to the Department as provided in 175 NAC 7-003.01B;
4. Receive approval in writing, from the Department, of schematic plan and, if new construction, of construction plans; and
5. Notify the Department at least 30 working days prior to planned patient occupancy.

7-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the health clinic to be licensed, street and mailing address, telephone number and facsimile number, if any;
2. Type of health clinic to be licensed;
3. Name of the administrator;
4. Name and address(es) of the health clinic owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the health clinic. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the health clinic. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 7;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number, if the applicant is an individual (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document);
12. Signature(s) of:
 - a. The owner, if the applicant is an individual or partnership;
 - b. Two of its members, if the applicant is a limited liability company;
 - c. Two of its officers, if the applicant is a corporation; or
 - d. The head of the governmental unit having jurisdiction over the health clinic to be licensed, if the applicant is a governmental unit;
13. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
14. Schematic plans;
15. For new construction, construction plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. An applicant may construct a project description and/or certification document, or obtain a form from the Department. Construction plans must include the following:
 - a. Project name, description of the project with quantity and floor area information on bed, care, treatment, and toileting locations, building systems, medical equipment, street address, and contact person;

- b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;
 - c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
 - d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
 - e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 7-007;
- 16. Planned occupancy date;
 - 17. Copies of zoning approval from the relevant jurisdiction;
 - 18. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
 - 19. Required licensure fee specified in 175 NAC 7-004.09.

7-003.01C Department Responsibilities: The Department will:

- 1. Review the application for completeness;
- 2. Provide notification to the applicant of any information needed to complete the application;
- 3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 7-007;
- 4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 7-005 prior to the issuance of a health clinic license; and
- 5. Issue or deny a license based on the results of the initial inspection.

7-003.01D Denial of License: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's denial of an initial license.

7-003.02 Renewal Licenses

7-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application, or obtain an application form from the Department. The application must include:

- 1. Full name of the health clinic to be licensed, street and mailing address, telephone number, and facsimile number, if any;
- 2. Type of health clinic to be licensed;
- 3. Name of the administrator;
- 4. Name and address(es) of the health clinic or service owner(s);
- 5. Ownership type;

6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the health clinic. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the health clinic. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 7;
10. Applicant's federal employer identification number, if an individual;
11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
12. Number of patient admissions in the past year;
13. Signature(s) of:
 - a. The owner, if the applicant is an individual or partnership;
 - b. Two of its members, if the applicant is a limited liability company;
 - c. Two of its officers, if the applicant is a corporation; or
 - d. The head of the governmental unit having jurisdiction over the health clinic to be licensed, if the applicant is a governmental unit;
14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
15. Required licensure fee as specified in 175 NAC 7-004.09.

7-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
 - a. Date of expiration;
 - b. Fee for renewal;
 - c. License number; and
 - d. Name and address of the health clinic.
2. Issue a renewal when it determines that the licensee has submitted a completed application;

3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:
 - a. The licensee failed to pay the renewal fee or submit an application or both;
 - b. The license has expired;
 - c. The Department will suspend action for 30 days following the date of expiration;
 - d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
 - e. That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.
4. Place the health clinic license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the health clinic may not operate. The license remains in lapsed status until it is reinstated.

7-003.02C Refusal to Renew: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's refusal to renew a license.

7-003.03 Reinstatement from Lapsed Status: A health clinic requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 7-004.09. The application must conform to the requirements specified in 175 NAC 7-003.02.

7-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 7-006 and 7-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the health clinic has provided care or treatment from the site under a license that is different from the lapsed license.

7-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 7-005.

7-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

7-003.03D Refusal to Reinstatement: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

7-004 GENERAL REQUIREMENTS

7-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 7-006 and 7-007. A single license may be issued for:

1. A health clinic operating in separate buildings or structures on the same premises under one management;
2. An inpatient facility that provides services on an outpatient basis at multiple locations; or
3. A health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area served by the health clinic and sharing administration with the clinics.

7-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

7-004.03 Effective Date and Term of License: A health clinic license expires on the last day of February each year.

7-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the health clinic remains on the same premises, the inspection in 175 NAC 7-005 is not required. If there is a change of premises, the health clinic must pass the inspection specified in 175 NAC 7-005.

7-004.05 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a health clinic is sold, leased, discontinued, or moved to new premises.

7-004.06 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. To request a single license document;
2. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
3. If new construction is planned, and submit construction plans for Department approval prior to any new construction affecting patient care and treatment areas of the health clinic. The Department may accept certification from an architect or engineer in lieu of Department review;
4. Within 24 hours if a facility has reason to believe that a patient death was due to abuse or neglect by staff;
5. Within 24 hours of any clinic fire requiring fire department response; or

6. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients. This must include a description of the well-being of the clinic's patients and the steps being taken to assure patient safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the clinic's capacity to communicate.

7-004.07 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

7-004.08 Deemed Compliance

7-004.08A Accreditation or Certification: The Department may deem an applicant or licensee in compliance with 175 NAC 7-006 based on its accreditation or certification as a health clinic, ambulatory surgical center, provider of hemodialysis services, or provider of labor and delivery services by the:

1. Joint Commission on Accreditation of Healthcare Organizations;
2. Accreditation Association of Ambulatory Health Care; or
3. Medicare or Medicaid certification program.

7-004.08A1 An applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 7-006 based on accreditation or certification. The request must be:

1. Made in writing;
2. Submitted within 30 days of receipt of a report granting accreditation or certification; and
3. Accompanied by a copy of the accreditation or certification report.

7-004.08A2 Upon receipt of the request, the Department will deem the facility in compliance with 175 NAC 7-006 and will provide written notification of the decision to the facility within ten working days of receipt of the request.

7-004.08A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 7-006 from the random selection of up to 25% of facilities for compliance inspections under 175 NAC 7-005.04A. The facility may be selected for a compliance inspection under 175 NAC 7-005.04B.

7-004.08A4 To maintain deemed compliance, the licensee must maintain the accreditation or certification on which the license was issued. If the accreditation or certification has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the health clinic may continue to operate unless the Department determines that the health clinic no longer meets the requirements for licensure under the Health Care

Facilities Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 7-005.

7-004.09 Fees: The Department will charge fees for licensure as set forth below:

7-004.09A Initial Licensure Fee:

1. All types of health clinics except public health clinics and ambulatory surgical centers: \$600
2. Public health clinics: \$400
3. Ambulatory surgical centers:
 - a. 1 operating/procedure room \$1,250
 - b. 2 to 3 operating/procedure rooms \$1,350
 - c. 4 or more operating/procedure rooms \$1,450

7-004.09B Renewal Licensure Fees:

1. All types of health clinics except public health clinics and ambulatory surgical centers:
 - a. 1 to 50 patient admissions in the past year \$600
 - b. 51 to 100 patient admissions in the past year \$800
 - c. 101 or more patient admissions in the past year \$1,000
2. Public health clinics:
 - a. 1 to 50 patient admissions in the past year \$400
 - b. 51 to 100 patient admissions in the past year \$450
 - c. 101 or more patient admissions in the past year \$500
3. Ambulatory surgical centers:
 - a. 1 operating/procedure room \$1,250
 - b. 2 to 3 operating/procedure rooms \$1,350
 - c. 4 or more operating/procedure rooms \$1,450
 - d. All ambulatory surgical centers must also pay an additional fee under the Outpatient Surgical Procedures Data Act, Neb. Rev. Stat. §§ 81-6,111 to 81-6,119, as follows:
 - (1) 500 or fewer outpatient surgeries per year \$275
 - (2) 501 to 2,000 outpatient surgeries per year \$350
 - (3) More than 2,000 outpatient surgeries per year \$425

7-004.09C Duplicate original license: \$ 10

7-004.09D Refunds for denied applications:

1. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of \$25; or
2. If the Department performed an inspection, the fee is not refunded.

7-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the health clinic prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

7-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 7-006 and 7-007. The inspection will occur within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the health clinic within ten working days after completion of an inspection.

7-005.02 Results of Initial Inspection

7-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 7-006 and 7-007, the Department will issue a license.

7-005.02B When the Department finds that the applicant had complied substantially but has failed to comply fully with the requirements of 175 NAC 7-006 and 7-007 and the failure(s) would not pose an imminent danger of death or physical harm to persons served by the health clinic, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

7-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons served by the health clinic, the Department may send a letter to the health clinic requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the health clinic submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

7-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the health clinic submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or
2. If the health clinic fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

7-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 7-006 and 7-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

7-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 7-007 at new facilities or new construction prior to use or occupancy.

7-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

7-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 7, and that the health clinic is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

7-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the health clinic;
6. Name(s) of the owner(s) of the health clinic;
7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety

equipment are completed in accordance with approved construction plans; and

9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 7-007, and approved for use and occupancy.

7-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying that the facility meets the codes specified in 175 NAC 7-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations, and life safety information.

7-005.04 Compliance Inspections: The Department may, following the initial licensure of a health clinic, conduct an unannounced onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 7-006 and 7-007. The inspection may occur based on random selection or focused selection.

7-005.04A Random Selection: Each year the Department may inspect up to 25% of the health clinics based on a random selection of licensed health clinics.

7-005.04B Focused Selection: The Department may inspect a health clinic when the Department is informed of one or more of the following:

1. An occurrence resulting in patient death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 7;
6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the health clinic;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management, or ownership;
10. Change of status of accreditation or certification on which licensure is based as provided in 175 NAC 7-004.08; or
11. Any other event that raises concerns about the maintenance, operation, or management of the health clinic.

7-005.05 Results of Compliance Inspections

7-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of persons served by the health clinic, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 7-008.03.

7-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of persons served by the health clinic, the Department may request a statement of compliance from the health clinic. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the health clinic submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or
2. If the health clinic fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the health clinic license, in accordance with 175 NAC 7-008.

7-005.06 Re-inspections

7-005.06A The Department may conduct re-inspections to determine if a health clinic fully complies with the requirements of 175 NAC 7-006 and 7-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

7-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 7-008.02; or
4. Grant full reinstatement of the license.

7-006 STANDARDS OF OPERATION, CARE AND TREATMENT: 175 NAC 7-006 applies to the following types of health clinics unless specified otherwise: public health clinics, ambulatory

surgical centers, facilities at which ten or more abortions are performed during any one calendar week, facilities providing hemodialysis, and facilities providing labor and delivery services. Each health clinic must organize, manage, and administer in a manner consistent with the size, resources, and type of services to assure each patient receives the necessary care and treatment.

7-006.01 Licensee Responsibilities: The licensee of each health clinic must assume the responsibility for the total operation of the facility. The licensee responsibilities include:

1. Monitoring policies to assure the appropriate administration and management of the health clinic;
2. Maintaining the health clinic's compliance with all applicable state statutes and relevant rules and regulations;
3. Providing quality care and treatment to patients whether care and treatment are furnished by health clinic staff or through a contract with the health clinic;
4. Periodically reviewing reports and recommendations regarding the Quality Assurance/Performance Improvement program and implementing programs and policies to maintain and improve the quality of patient care and treatment;
5. Maintaining written minutes of meetings and actions;
6. Designating an administrator who is responsible for the day to day management of the health clinic and defining the duties and responsibilities of the administrator in writing;
7. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs including who will be responsible for the position until another administrator is appointed;
8. Notifying the Department in writing within five working days when the vacancy is filled including effective date and name of person appointed administrator; and
9. Determining if emergency medical technician-intermediates or emergency medical technician-paramedics may perform activities within their scope of practice as either an employee or volunteer within the health clinic.

7-006.02 Administration: The administrator is responsible for planning, organizing, and directing the day to day operation of the health clinic. The administrator must report in all matters related to the maintenance, operation and management of the health clinic and be directly responsible to the licensee or to the person or persons delegated governing authority by the licensee. The administrator's responsibilities include:

1. Being on the premises a sufficient number of hours to permit adequate attention to the management of the health clinic;
2. Providing for the protection and promotion of patients' health, safety, and well-being;
3. Maintaining staff appropriate to meet patient needs;

4. Designating a substitute, who is responsible and accountable for management of the health clinic, to act in the absence of the administrator; and
5. Developing procedures which require the reporting of any evidence of abuse, neglect or exploitation of any patient served by the health clinic in accordance with Neb. Rev. Stat. § 28-372 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. § 28-711.
6. Determining the supervision of and training for emergency medical technician-intermediates or emergency medical technician-paramedics.

7-006.03 Staff Requirements: Each health clinic must maintain a sufficient number of staff with the qualifications, training, and skills to meet operational and patient needs. Each health clinic must have job descriptions for each staff position, which include minimum qualifications required for the position.

7-006.03A Employment Eligibility: Each health clinic must ensure and maintain evidence of the following:

7-006.03A1 Staff Credentials: Each health clinic must verify:

1. The current active licensure, registration, certification or other credentials in accordance with applicable state law, prior to staff assuming job responsibilities and must have procedures for verifying that the current status is maintained; and
2. That an emergency medical technician-intermediate or an emergency medical technician-paramedic providing service in the health clinic is employed by or serving as a volunteer member of an emergency medical service licensed by the Department.

7-006.03A1a If unlicensed staff assist in provision of care or treatment, such staff must be supervised by the appropriate licensed health care professional.

7-006.03A2 Health Status: Each health clinic must establish and implement policies and procedures related to the health status of staff to prevent the transmission of disease to patients.

7-006.03A2a Each health clinic must complete a health history screening for all staff prior to assuming job responsibilities and must require staff to have a physical examination when the results of the health history screening indicate the examination is necessary.

7-006.03A3 Criminal Background and Registry Checks: Each health clinic must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.

7-006.03A3a Criminal Background Checks: The health clinic must complete a criminal background check through a governmental law

enforcement agency or a private entity that maintains criminal background information.

7-006.03A3b Registry Checks: The health clinic must check for adverse findings on each of the following registries:

1. Nurse Aide Registry;
2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

7-006.03A3c The health clinic must:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to patient safety or patient property.

7-006.03A3d The health clinic must not employ a person with adverse findings on the Nurse Aide Registry regarding patient abuse, neglect, or misappropriation of patient property.

7-006.03B Training: Each health clinic must ensure staff receive training in order to perform job responsibilities.

7-006.03B1 Orientation: Each health clinic must provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program must include an explanation of the:

1. Job duties and responsibilities;
2. The health clinic's sanitation and infection control program;
3. Organizational structure;
4. Patient Rights;
5. Patient care policies and procedures;
6. Personnel policies and procedures;
7. Emergency procedures;
8. Disaster preparedness plan; and
9. Reporting requirements for abuse, neglect and exploitation in accordance with the Adult Protective Services Act, Neb. Rev. Stat. § 28-372 or in the case of a child in accordance with Neb. Rev. Stat. § 28-711 and with health clinic policies and procedures.

7-006.03B1a Each health clinic that approves emergency medical technician-intermediates and emergency medical technician-paramedics to provide service as either an employee or a volunteer must provide orientation to registered nurses, physicians, and physician assistants involved in the supervision of emergency medical technician-intermediates and emergency medical technician-paramedics. The orientation must include:

1. Information regarding the scope of practice of an emergency medical technician-intermediate or emergency medical technician-paramedic; and
2. Supervision requirements, as determined by the governing authority of the health clinic, for emergency medical technician-intermediates and emergency medical technician-paramedics, to perform activities within their scope of practice as defined in 172 NAC 11, Regulations Governing Out-of-Hospital Emergency Care Providers, Section 11-006.

7-006.03B2 Ongoing Training: Each health clinic must maintain evidence of ongoing/continuous inservices or continuing education provided for staff. A record must be maintained including date, topic and participants. Specialized training of staff to permit performance of particular procedures or to provide specialized care, whether as part of a training program or as individualized instruction, must be documented in personnel records.

7-006.03C Employment Record: Each health clinic must maintain a current employment record for each staff person. The record must include information on orientation, inservice, credentialing and health history screening.

7-006.04 Patient Rights: Each health clinic must protect and promote each patient's rights. This includes the establishment of written policies and procedures and enforcement of such to ensure the operations of the clinic afford patients the opportunity to exercise their rights. At a minimum, each patient must have the right to:

1. Respectful and safe care by competent personnel;
2. Be informed of patient rights during the admission process;
3. Be informed in advance about care and treatment and related risks;
4. Make informed decisions regarding care and treatment and to receive information necessary to make those decisions;
5. Refuse care and treatment and to be informed of the medical consequences of refusing such;
6. Formulate advance directives and to have the health clinic comply with the directives unless the clinic notifies the patient of the inability to do so;
7. Personal privacy and confidentiality of medical records;
8. Be free from abuse, neglect and exploitation;
9. Access information contained in his/her medical record within a reasonable time when requested;

10. Receive health clinic services without discrimination based upon race, color, religion, gender, national origin, or payer. Health clinics are not required to provide uncompensated or free care and treatment unless otherwise required by law; and
11. Voice complaints and grievances without discrimination or reprisal and have those complaints and grievances addressed.

7-006.04A Grievances: Each health clinic must establish and implement a process that promptly addresses grievances filed by patients or their designee. The process, includes, but is not limited to:

1. A procedure for submission of grievances that is made available to patients or representatives;
2. Time frames and procedures for review of grievances and provision of a response; and
3. How information from grievances and responses are utilized to improve the quality of patient care and treatment.

7-006.05 Quality Assurance/Performance Improvement: Each health clinic must have an effective quality assurance/performance improvement program to evaluate care and treatment provided to patients. The program includes, but is not limited to:

1. A written plan of implementation;
2. Evaluation of care and treatment provided both by staff and through contract;
3. For ambulatory surgical centers, the tracking of surgical procedures that result in unplanned patient admissions to a hospital within 72 hours of a procedure, due to post surgical complications;
4. Appropriate action to address problems found through the program;
5. Evaluation of the outcome of any action taken; and
6. Reporting to the governing authority.

7-006.06 Patient Care and Treatment: Each health clinic must establish and implement written policies and procedures that encompass all care and treatment provided to patients. The policies and procedures are consistent with prevailing professional standards, delineate the scope of services provided in the health clinic and encompass aspects to protect the health and safety of patients.

7-006.06A Administration of Medications: Each health clinic must establish and implement policies and procedures to ensure patients receive medications only as legally prescribed by a medical practitioner in accordance with the Five Rights and prevailing professional standards.

7-006.06A1 Methods of Administration of Medications: When the health clinic is responsible for the administration of medications, it must be accomplished by the following methods:

7-006.06A1a Self Administration: The health clinic must allow patients of the health clinic to self-administer medications, with or without

supervision, when assessment determines the patient is capable of doing so.

7-006.06A1b Licensed Health Care Professional: When the health clinic utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the health clinic must ensure the medications are properly administered in accordance with prevailing professional standards.

7-006.06A1c Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the health clinic utilizes persons other than a licensed health care professional in the provision of medications, the health clinic must follow 172 NAC 95 Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96 Regulations Governing the Medication Aide Registry. Each health clinic must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004.
2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005.
3. That specify how direction and monitoring will occur when the health clinic allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:
 - a. Provide routine medication; and
 - b. Provision of medications by the following routes:
 - (1) Oral, which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
 - (2) Inhalation which includes inhalers and nebulizers, including oxygen given by inhalation;
 - (3) Topical application of sprays, creams, ointments, and lotions, and transdermal patches; and

- (4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose.
- 4. That specify how direction and monitoring will occur when the health clinic allows medication aides to perform the additional activities authorized by 172 NAC 95-009, which include but are not limited to:
 - a. Provision of PRN medications;
 - b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
 - c. Participation in monitoring.
- 5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision.
- 6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009.
- 7. That specify how records of medication provision by medication aides will be recorded and maintained.
- 8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:
 - a. Made to the identified person responsible for direction and monitoring;
 - b. Made immediately upon discovery; and
 - c. Documented in patient medical records.

7-006.06A2 Each health clinic must establish and implement policies and procedures for reporting any errors in administration or provision of prescribed medications to the prescriber in a timely manner upon discovery and a written report of the error must be prepared and maintained.

7-006.06A3 Each health clinic must establish and implement policies and procedures for reporting any adverse reaction to a medication, in a timely manner upon discovery, to the prescriber and for documenting such event in the patient's medical record.

7-006.06A4 Each health clinic must establish and implement procedures to ensure patients receive medications as prescribed by a medical practitioner. At a minimum, the following must be evident:

1. A current policy and procedure manual regarding the handling of medications in the health clinic;
2. A count of all controlled substances in the health clinic every 24 hours; and
3. Only authorized personnel designated by health clinic policy are allowed access to medications.

7-006.06B Verbal Orders: Each health clinic must establish and implement appropriate policies and procedures for those staff authorized to receive telephone and verbal diagnostic and therapeutic orders.

7-006.06C Patient Education: Each health clinic must establish and implement a process to ensure patients and/or their designee receive appropriate education and instruction to assist in understanding the identified condition and the necessary care and treatment. Any instructions at the time of discharge must be given in writing.

7-006.06D Patient Transfers: Each health clinic must transfer to a health care facility and have procedures for continued care of any patient whose condition does not allow dismissal within 24 hours.

7-006.07 Record Keeping Requirements: Each health clinic must maintain records and reports in such a manner to ensure accuracy and easy retrieval.

7-006.07A Medical Records: Every patient who receives care or treatment in a health clinic must have a medical record established. Medical records must contain sufficient information to clearly identify the patient and document the diagnosis, care, treatment, and results accurately.

7-006.07A1 Content: Medical records must contain, when applicable, the following information:

1. Identification data;
2. Chief complaint;
3. Medical history;
4. Physical examination;
5. All pathology/laboratory and radiology reports;
6. Properly executed informed consent forms;
7. Consultation reports;
8. Medical practitioner orders;
9. Care and treatment provided;
10. Progress notes;
11. Pertinent observations and events; and
12. Instructions to patients, including discharge/dismissal.

7-006.07A2 Medical records must contain entries which are dated, legible, and indelible. The author of each entry must be identified and authenticated. Authentication must include signature, written initials, or computer entry.

7-006.07A3 Retention: Each health clinic must maintain and preserve all medical records in original, microfilm, electronic, or other similar form, for a period of at least five years. In the case of a minor, the medical records must be kept until three years after the age of majority has been attained. When a health clinic ceases operation, all medical records must be transferred as directed by the patient or authorized representative to the licensed health care facility or health care service to which the patient is transferred. All other medical records that have not reached the required time for destruction must be stored to assure confidentiality and the Department must be notified of the address where stored.

7-006.07A4 Confidentiality: Medical records must be kept confidential, available only for use by authorized persons or as otherwise permitted by law. Records must be available for examination by authorized representatives of the Department.

7-006.07A5 Access: Patient information and/or records will be released only with consent of the patient or designee or as required by law.

7-006.07A6 Destruction: Medical records may be destroyed only when they are in excess of five years of age. In order to ensure confidentiality, each health clinic must destroy or dispose of medical records by shredding, incineration, electronic deletion, or another equally effective protective measure.

7-006.07B Other Records/Reports: In addition to patient medical records, each health clinic must maintain accurate and complete administrative records of the clinic operation for not less than three years unless longer is required by law.

7-006.07B1 A report that summarizes the scope and volume of services provided at the health clinic each year must be maintained.

7-006.08 Infection Control: Each health clinic must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

7-006.08A The infection control program must include, but is not limited to:

1. The responsible person(s) for the program;
2. A system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and staff;
3. A definition of nosocomial infection;
4. A system for reporting known or suspected cases of infection acquired at the health clinic among patients and for maintaining records of such infection;
5. Maintenance of a record of infection, communicable disease and nosocomial infections;

6. Implementation of corrective action plans; and
7. Mechanism for evaluation of the program.

7-006.08A Equipment and Supplies: Each health clinic must establish and implement written policies and procedures for cleaning, sterilization and storage of supplies and equipment. Equipment and supplies must be maintained in accordance with prevailing professional standards to protect patients from infection.

7-006.08B Handwashing: Facilities for handwashing must be easily accessible and good handwashing techniques must be practiced by staff before and after patient contact.

7-006.08C Food Service: Each health clinic that provides food service must store, prepare, protect, and dispose of food in a safe and sanitary manner and in accordance with the Food Code.

7-006.09 Pharmacotherapy Services: Each health clinic that provides pharmacotherapy services to meet patient needs must maintain drugs, devices, and biologicals under the supervision of a licensed Nebraska pharmacist or licensed Nebraska physician. The storage, control, handling, compounding, administration, provision, and dispensing of drugs, devices, and biologicals must be in accordance with state and federal law.

Any health clinic that conducts a pharmacy or engages in the practice of pharmacy must do so in accordance with Neb. Rev. Stat. §§ 71-1,142 to 71-1,147.61.

Each health clinic must ensure that information relating to interactions, contraindications, side effects, toxicology, dosage, indications for use, and routes of administration for drugs, devices, and biologicals is available to staff at all times.

7-006.09A Emergency Drugs, Devices, and Biologicals: Emergency drugs, devices, and biologicals, as determined by the need of patients served by each health clinic, must be readily available for use when an emergency occurs.

7-006.09B Prescribing Drugs, Devices, and Biologicals: Each health clinic must establish appropriate policies and procedures for those personnel authorized to receive telephone and verbal orders for drugs, devices, and biologicals. A separate policy and procedure must be required in health clinics where drugs, devices, and biologicals are dispensed to patients. All written orders and prescriptions must be legible as required by 175 NAC 7-006.07A1.

7-006.09C Preparation and Compounding of Drugs, Devices, and Biologicals: A current policy and procedure manual regarding the handling of drugs, devices and biologicals in the health clinic must be available at all times to personnel authorized to administer or provide such. The manual must include information on preparation and must comply with all state and federal law regarding the practice of pharmacy.

7-006.09D Dispensing of Drugs, Devices, and Biologicals: All drugs, devices, and biologicals dispensed from a health clinic must be dispensed by a pharmacist, a

physician with a dispensing permit, or in accordance with Neb. Rev. Stat. §§ 71-1,147.39 to 71-1,147.61.

7-006.09E Storage of Drugs, Devices, and Biologicals: All drugs, devices, and biologicals must be stored in secured areas and stored in accordance with the manufacturer's, distributor's, packager's, or dispensing pharmacist's instructions for temperature, light, humidity, and other storage instructions. Only authorized personnel, designated by policy and procedure of the health clinic as responsible for administration, provision, or dispensing, must have access to drugs, devices, and biologicals. The supply of drugs, devices, and biologicals must be protected and restricted to use for legally authorized purposes and must be checked on a regular basis to ensure expired, mislabeled, unlabeled, or unusable products are not available for patient use.

7-006.09F Record Keeping: All drugs, devices, and biologicals administered, provided, or dispensed for a patient must be recorded in the patient's medical record. The record must specify the name, dosage, date, time, and route of administration or provision and identification of the person who administered or provided such.

7-006.09F1 A complete and accurate record of all drugs, devices, and biologicals received, stored, administered, provided, dispensed, or disposed of by the health clinic must be kept and maintained for not less than five years.

7-006.09F2 Each health clinic must have a policy and procedure for the reporting and recording of any abuse or loss of drugs, devices, and biologicals. Such policy must be in accordance with state and federal law concerning abuse and loss of drugs, devices, and biologicals.

7-006.09G Sample Drugs, Devices, and Biologicals: Personnel of a health clinic must not receive manufacturer, distributor, or packager samples in violation of any state or federal law.

7-006.09G1 A complete and accurate record of all drugs, devices, and biologicals samples received, stored, administered, provided, dispensed, or disposed of by the health clinic must be kept and maintained for not less than five years.

7-006.09G2 All samples administered, provided, or dispensed to a patient must be recorded in the patient's medical record.

7-006.09H Investigational Drugs, Devices, and Biologicals: All drugs, devices, and biologicals being used as a part of a clinical investigation must be maintained in a locked and separate area from all other drugs, devices, and biologicals. All investigational drugs, devices, and biologicals should be administered only in accordance with the clinical study protocol.

7-006.09I Disposal of Drugs, Devices, and Biologicals: Each health clinic must ensure that expired, mislabeled, unlabeled, or unusable drugs, devices, and biologicals are not available for patient use and are disposed of in accordance with clinic policies and state and federal law. The disposal must be conducted on a routine basis to prevent storage of large quantities of expired, mislabeled, unlabeled, or unusable drugs, devices, and biologicals.

7-006.10 Laboratory Services: All laboratory testing, whether provided directly by the health clinic or through agreement, must comply with the Clinical Laboratory Improvement Amendments of 1988 as amended (CLIA).

7-006.10A Complete laboratory test result reports must be kept in patient medical records.

7-006.11 Radiology Services: Each health clinic that provides radiology services must be under the direction of a physician and must comply with the provisions of Neb. Rev. Stat. §§ 71-3501 to 71-3520 of the Radiation Control Act and the regulations promulgated thereunder.

7-006.11A Personnel performing medical radiography procedures must be licensed in accordance with Neb. Rev. Stat. §§ 71-3515.01 to 71-3515.02 of the Radiation Control Act and the regulations promulgated thereunder.

7-006.12 Ambulatory Surgical Center: Each ambulatory surgical center must meet the regulations specified in 175 NAC 7-006.01 to 7-006.09 and 7-006.15. In addition, each ambulatory surgical center must meet all requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare as an ambulatory surgical center as defined in 42 CFR 416.1 to 416.200 attached to these regulations and incorporated by this reference.

7-006.12A Each ambulatory surgical center is limited to performing surgical and other medical procedures that can be safely performed in a dedicated operating room or suite and which may require a postoperative recovery room for convalescent stay. An ambulatory surgical center can only provide surgical services to persons who are admitted to and discharged from the ambulatory surgery center within the same working day and must not retain patients past midnight of the day of admission.

7-006.12B Each ambulatory surgical center must maintain a chronological permanent admission and discharge record that, at a minimum, includes:

1. Full name of each patient;
2. Identification number assigned by the ambulatory surgical center;
3. Date and time of admission and discharge;
4. Surgical procedure(s) performed;
5. Inclusive time of surgical procedure(s);
6. Name of surgeon and any assistants(s);

7. Name of nursing personnel (scrubbing and circulating);
8. Type of anesthesia; and
9. Name and title of person administering anesthesia.

7-006.12C Each ambulatory surgical center must provide discharge planning to patients or their designee.

7-006.12C1 If a patient is discharged to a health care facility or health care service, necessary medical information must be transferred to the receiving facility or service.

7-006.12D Before discharge from the ambulatory surgical center, the patient must be evaluated for proper recovery. Qualified personnel must remain with the patient until the patient's status is stable and protective reflexes have returned to normal. A patient may be discharged only when a medical practitioner and facility policies determine it is safe and appropriate to discharge. The ambulatory surgical center must establish medical criteria for discharge which is consistent with prevailing professional standards.

7-006.12E Each ambulatory surgical center must, at least annually, provide surgeons performing surgery at the facility a report as to the number and rates of surgical infections in patients of the surgeons.

7-006.13 Hemodialysis Services: Each health clinic providing hemodialysis services must be licensed as a health clinic and must meet the regulations specified in 175 NAC 7-006.01 to 7-006.11 and 7-006.15. In addition, each health clinic must meet all requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare for hemodialysis services as defined in 42 CFR 405.2100 to 405.2163, attached to these regulations and incorporated by this reference.

7-006.14 Labor and Delivery Services: Each facility, not licensed as a hospital, that provides labor and delivery services must be licensed as a health clinic and must meet the regulations specified in 175 NAC 7-006.01 to 7-006.11; 7-006.15 and the following requirements:

7-006.14A Care and Treatment: Each facility must establish and implement written policies and procedures to ensure the safe delivery of care and treatment to patients. The policies and procedures must include, but are not limited to, the following:

1. Care and treatment during antepartum, intrapartum, postpartum, and newborn care;
2. Appropriate attire to be worn during labor and delivery;
3. The use of oxytocic drugs and administration of anesthetics, sedatives, analgesics, and other drugs, devices, and biologicals;
4. Visitation and attendance during the birth process; and
5. Method for identification of every newborn immediately after birth.

7-006.14B Staff: Each facility must have a sufficient number of qualified staff to meet the needs of patients. The staff must function in accordance with their scope of practice.

7-006.14B1 Appropriate licensed health care professional staff must be on call at all times and available on-site at the facility within 30 minutes.

7-006.14B2 Nursing care during labor and delivery including care of the newborn must be supervised by a qualified registered nurse.

7-006.14B3 The direction and coordination of all medical aspects of the facility's policies must be by a physician designated by the governing authority.

7-006.14B4 At least one physician, certified nurse midwife, or registered nurse must be present at all times when a mother or newborn is in the facility.

7-006.14C Emergency Equipment and Supplies: Each facility must have the necessary, drugs, devices, biologicals, equipment, and supplies immediately available for provision of care and treatment should an equipment emergency arise.

7-006.14C1 The following emergency equipment must be available in the facility to provide care to both adults and newborns:

1. Emergency call system;
2. Oxygen;
3. Mechanical ventilation assistance equipment including airways and manual breathing bags;
4. Cardiac defibrillator;
5. Cardiac monitoring equipment;
6. Tracheotomy sets;
7. Laryngoscopes and endotracheal tubes; and
8. Suction equipment.

7-006.14D Emergency Transfer: Each facility must have a written agreement for emergency care with a hospital that provides obstetrical services or each medical practitioner practicing at the facility must have admitting privileges at a transferring hospital.

7-006.14D1 Each facility must have the capability to transfer and transport the mother and/or newborn to the contract hospital(s) timely or have a written contract with an ambulance service that will assure timely response.

7-006.14E Admission and Discharge: Each facility must establish and implement criteria for rejection, admission, discharge, and continuing care of patients which is clearly defined and made available for review to persons requesting such.

7-006.14E1 Admissions to the facility must be restricted to low-risk patients who have received antepartum care in accordance with the facility's policies.

7-006.14E2 Planned Caesarean Section procedures are prohibited.

7-006.14E3 Each mother and newborn must be discharged within 24 hours after admission, in a condition which will not endanger the well-being of either. If the condition of mother or newborn does not allow discharge within 24 hours, then transfer to a hospital must occur.

7-006.14E4 Verbal and written instructions must be provided for observation and care of both the mother and newborn after discharge. The mother and newborn must be discharged in the care of the father or a responsible adult who will assist in their transport from the facility.

7-006.14F Records: Each facility must maintain a permanent admission and discharge patient index that includes, but is not limited to:

1. Full name of patient and identification number assigned by the facility;
2. Date and time of admission and discharge;
3. Name of admitting physician or certified nurse midwife;
4. Type of anesthesia;
5. Time of birth;
6. Gender of newborn; and
7. Disposition or place to which mother and newborn were discharged/transferred.

7-006.14G All births must be reported in accordance with Neb. Rev. Stat. § 71-604.

7-006.15 Environmental Services: Each health clinic must provide a safe, clean, and comfortable environment for patients. Every detached building on the same premises used for care and treatment must comply with 175 NAC 7.

7-006.15A Housekeeping and Maintenance: The facility must provide the necessary housekeeping and maintenance to protect the health and safety of patients.

7-006.15A1 The facility's buildings and grounds must be kept clean, safe and in good repair.

7-006.15A2 All garbage and rubbish must be disposed of in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin. Garbage must be disposed in such a manner as to minimize the transmission of infectious diseases and minimize odor.

7-006.15A3 The facility must maintain adequate lighting, environmental temperatures, and sound levels in all areas that are conducive to the care and treatment provided.

7-006.15A4 The facility must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

7-006.15B Equipment, Fixtures, and Furnishings: The facility must provide and maintain all equipment, fixtures, and furnishings clean, safe and in good repair.

7-006.15B1 The facility must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that such equipment and furnishings are safe and function to meet the intended use.

7-006.15C Linens: The facility must maintain an adequate supply of linen necessary for the care and treatment of patients. Linen must be clean and in good repair.

7-006.15C1 The facility must establish and implement procedures for the storage and handling of soiled and clean linens.

7-006.15C2 When the facility provides laundry services, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with manufacturer's instructions.

7-006.15D Pets: The health clinic must assure any facility owned pet does not negatively affect patients. The health clinic must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current vaccination for rabies for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks and other parasites; and
4. Responsibility for care and supervision of the pet by health clinic staff.

7-006.15E Environmental Safety: The health clinic must be responsible for maintaining the environment in a manner that minimizes accidents.

7-006.15E1 The facility must maintain the environment to protect the health and safety of patients by keeping surfaces smooth and free of sharp edges, mold, or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.

7-006.15E2 The facility must maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care and treatment.

7-006.15E3 The facility must provide water for bathing and handwashing at safe and comfortable temperatures to protect patients from potential for burns or scalds.

7-006.15E3a The facility must monitor and maintain water temperatures that accommodate comfort and preferences but not to exceed the following temperatures:

1. Water temperature at patient handwashing fixtures must not exceed 120 degrees Fahrenheit.
2. Water temperatures at bathing and therapy fixtures must not exceed 110 degrees Fahrenheit.

7-006.15E4 The facility must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by patients.

7-006.15E5 The facility must restrict access to mechanical equipment which may pose a danger to patients.

7-006.15F Disaster Preparedness and Management: The health clinic must establish and implement disaster preparedness plans and procedures to ensure that patient care and treatment, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) and other disasters, disease outbreaks, or other similar situations causing patients to remain at the clinic. Such plans and procedures must address and delineate:

1. How the clinic will maintain the proper identification of each patient to ensure that care and treatment coincide with the patient's needs;
2. How the clinic will move patients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;
3. How the clinic will protect patients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;
4. How the clinic will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and
5. How the clinic will provide for the comfort, safety, and well-being of patients in the event of 24 or more consecutive hours of:
 - a. Electrical or gas outage;

- b. Heating, cooling, or sewer system failure, or
- c. Loss or contamination of water supply.

7-007 PHYSICAL PLANT STANDARDS: All health clinics must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The physical plant standards for health clinics, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

7-007.01 Support Areas: The health clinic may share the following support areas among detached structures, care and treatment areas, or with other licensed facilities.

7-007.01A Dietary: If food preparation is provided on site, the facility must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code.

7-007.01B Laundry: If the facility provides laundry services, the service may be provided by contract or on-site by the facility.

7-007.01B1 Contract: If contractual services are used, the facility must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

7-007.01B2 On-site: If on-site services are provided, the facility must have areas dedicated to laundry.

7-007.01B2a In new construction, if the facility processes bulk laundry, the laundry must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms with a separate soaking and hand washing sink in the laundry area.

7-007.01B2b Separate clean linen supply storage facilities must be conveniently located to care and treatment locations.

7-007.01C Diagnostic: If the facility provides radiology or laboratory services, the services must comply with the following:

7-007.01C1 Imaging rooms must accommodate the operational and shielding requirements of the equipment installed, condition of the patient, and provide clear floor area adequate for the safety of staff and patients.

7-007.01C2 Laboratory areas must provide for sample collection and protection, analyzing, testing, and storage. The facility must handle all potentially contagious and hazardous samples in a manner as to minimize transmission of infectious diseases.

7-007.01D Waste Processing: The health clinic must provide areas to collect,

contain, process, and dispose of medical and general waste produced within the health clinic in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

7-007.01E Housekeeping Room: The facility must have a room with a service sink and space for storage of supplies and housekeeping equipment.

7-007.02 Care and Treatment Areas: The health clinic must not share the following care and treatment areas among detached structures or with other facilities operated by another licensee. Care and treatment areas must comply with the following:

7-007.02A Staff Areas: Health clinics that provide nursing services must provide the following support areas for each distinct patient care and treatment areas.

7-007.02A1 Control Point: The facility must have an area or areas for charting and patient records, and call and alarm annunciation systems.

7-007.02A2 Medication Station: The facility must have a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

7-007.02A3 Patient Facilities: The facility must have space for patient care, treatment, consultation, and waiting area.

7-007.02A4 Utility Area: The facility must have a work area where clean materials are assembled. The work area must contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. A facility must have separate work rooms or holding rooms for soiled materials. A work room for soiled materials must contain a fixture for disposing wastes and a handwashing sink.

7-007.02B Equipment and Supplies: The health clinic must have services and space to distribute, maintain, clean, and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the facility.

7-007.02B1 Durable Medical: The facility must ensure that the durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

7-007.02B2 Sterile Processing: If sterile processing is completed onsite, the facility must have areas for decontamination and sterilizing of durable medical instruments and equipment.

7-007.02B2a The facility must provide separate sterile processing and waste processing areas.

7-007.02B2b In new construction and where provided, central sterile processing service area(s), must have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The facility must have handwashing sinks in both clean and soiled rooms.

7-007.02B3 Required Equipment: The facility must provide equipment adequate for meeting the care and treatment needs of patients.

7-007.02B4 Equipment Storage: The facility must have space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

7-007.02C Surgery: A health clinic providing surgical services must have at least one operating or procedure room and the following support areas. In new construction and facilities with more than two surgery rooms, the following support areas and central processing areas must be located in restricted access areas:

1. Preoperative Patient Area: Preoperative patient area(s) must have sufficient space and equipment to accommodate both ambulatory and non-ambulatory patients. These areas must be under the direct visual control of the nursing staff.
2. Recovery Area: Recovery area(s) must contain a medication station, handwashing sink, charting area, provisions for bedpan cleaning, and equipment and supply storage space.
3. Dressing Area: The facility must have patient dressing and toilet rooms separate from staff gowning areas.
4. Housekeeping Room: The facility must have soiled utility and housekeeping areas exclusively for the surgical suite.

7-007.02D Emergency Care: A health clinic providing emergency services must have at least one procedure or treatment room. To support the provision of emergency care, the facility must have the following:

1. Entrance: A well marked, illuminated covered entrance at grade level for emergency vehicle and pedestrian access;
2. Waiting Area: Patient and visitor waiting area(s) that are in direct observation of the reception, triage, or control station, and have access to a public phone and drinking fountain;
3. Storage: Storage areas for general medical/surgical emergency supplies, medications, and equipment under staff control and out of the

path of normal traffic; and

4. Toilet Room: A patient toilet room with handwashing sink which is convenient to the procedure or treatment room(s).

7-007.02E Rehabilitation: A facility providing rehabilitation services must have at least one treatment room or cubicle, an area for specialized treatment and care, handwashing sink(s), storage for equipment and supplies, call system, medication storage, and distribution, and areas to allow for patient toileting, dressing, and consultation.

7-007.02F Obstetrics: A facility providing obstetric services must have at least one patient room, space, and equipment to allow for care and treatment of both mother and infant, handwashing sink, storage for equipment and supplies, call and alarm annunciation systems, medication storage, and distribution, and convenient accommodations for patient toileting, dressing, and consultation.

7-007.03 Construction Standards: All health clinics must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for such facilities are set forth below.

7-007.03A Codes and Guidelines

7-007.03A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12;
7. Design: Guidelines for Design and Construction of Hospitals and Health Care Facilities, Chapter 9, 2001 edition, published by the American Institute of Architects; and
8. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

7-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

7-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 7-007. The facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

7-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with 175 NAC 7, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

7-007.03C Interpretations: All dimension, sizes, and quantities; noted herein will be determined by rounding fractions to the nearest whole number.

7-007.03D Floor Area: Floor area is the space with ceilings at least seven feet in height and does not include areas such as enclosed storage, toilets, and bathing rooms, corridors, and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width will not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height with areas less than five feet in height, not included in the required floor area.

7-007.03E Bathing Rooms: If the facility provides a tub or shower for patient bathing, they must be equipped with hand grips or other assistive devices.

7-007.03F Toilet Rooms: The facility must provide at least one room with a toilet and sink for patient use.

7-007.03G Patient Rooms: The facility may provide rooms of the following types which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the patient.

7-007.03H Isolation Rooms: The number and type of isolation rooms in a health clinic must be determined by the facility and must ensure a safe environment for patients.

7-007.03I Observation Areas: If the facility provides medical observation or behavior intervention methods, the facility must provide one or more appropriately equipped rooms for patients needing close supervision. Each room must:

1. Have appropriate temperature control, ventilation, and lighting;
2. Be void of unsafe wall or ceiling fixtures and sharp edges;
3. Have a way to observe the patient, such as an observation window or if

- necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room;
4. Have a way to assure that the door cannot be held closed by the patient in the room which could deny staff immediate access to the room; and
 5. Be equipped to minimize the potential of the patient's escape, injury, suicide, or hiding of restricted substances.

7-007.03J Bassinets: Each bassinet must have a minimum floor area of 40 square feet with at least 3 feet between bassinets.

7-007.03K Cubicles: Patient care and treatment cubicles must have a minimum floor area of 60 square feet with at least 3 feet between bedsides and adjacent side walls.

7-007.03L Examination Rooms: Each examination room must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair.

7-007.03M Treatment Rooms: Treatment room for procedures performed under topical, local, or regional anesthesia without pre-operative sedation must have a minimum floor area of 120 square feet and a minimum of 10 feet clear dimension.

7-007.03N Procedure Rooms: Procedure rooms for invasive and minor surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs must have a minimum floor area of 200 square feet and a minimum of 14 feet clear dimension.

7-007.03O Operating Rooms: Operating rooms for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions must have a minimum floor area of 300 square feet and a minimum of 16 feet clear dimension.

7-007.03P Corridors: The facility corridors must be wide enough to allow passage and be equipped as needed by the patients with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

7-007.03Q Doors: The health clinic doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize patient injury.

7-007.03Q1 All toilet and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

7-007.03Q2 In new construction all toilet and bathing rooms used by patients with less than 50 square feet of clear floor area must not have doors that solely swing inward.

7-007.03Q3 Doors may prevent escape and create seclusion where therapeutically required, such as emergency protective custody, detoxification and psychiatric locations.

7-007.03R Outdoor Areas: Any outdoor area for patient usage provided by the facility must be equipped and situated to allow for patient safety and abilities.

7-007.03S Handwashing Sinks: The facility must provide a handwashing sink equipped with towels and soap dispenser in all examination, treatment, isolation, and procedure rooms; available to every four care and treatment cubicle locations; and one scrub sink near the entrance of each operating room.

7-007.03T Privacy: In multiple bed patient care and treatment rooms, visual privacy, and window curtains must be provided for each patient. In new construction and new facilities, the curtain layout must totally surround each care and treatment location which will not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage facilities.

7-007.03U Finishes: Room finishes in care and treatment areas must comply with the following:

1. Washable room finishes provided in procedure rooms, existing isolation rooms, sterile processing rooms, workroom, laundry, and food-preparation areas must have smooth, non-absorptive surfaces which are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic and lay-in ceilings, if used, must not interfere with infection control. Perforated, tegular, serrated cut, or highly textured tiles are not acceptable.
2. Scrubbable room finishes provided in operating rooms and new isolation rooms must have smooth, non-absorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.

7-007.04 Building Systems: Health clinics must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the patient.

7-007.04A Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe, and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

7-007.04A1 The collection, treatment, storage, and distribution potable water system of a facility that regularly serves 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179 Regulations Governing Public Water Systems.

7-007.04A2 The collection, treatment, storage and distribution potable water system of a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 3 and 4. The facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. The facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards.

7-007.04A3 The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

7-007.04A4 Continuously circulated filtered and treated water systems must be provided as required for the care and treatment equipment used in the health clinic.

7-007.04A5 The facility must maintain a sanitary and functioning sewage system.

7-007.04B Hot Water System: The facility must maintain hot and cold water to all hand washing and bathing locations. The hot water system must have the capacity to provide continuous hot water at temperatures as required by 175 NAC 7.

7-007.04C Heating and Cooling Systems: The facility must provide a heating and air conditioning system for the comfort of the patient and capable of maintaining the temperature in patient care and treatment areas as follows:

7-007.04C1 In existing and new facilities, the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and a temperature that does not exceed 85 degrees Fahrenheit during cooling conditions.

7-007.04C2 In new construction the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and a temperature that does not exceed 80 degrees Fahrenheit during cooling conditions.

7-007.04C3 In new construction, central air distribution, and return systems must have the following percent dust rated filters :

1. General areas: 30 +% ; and
2. Procedure and operating rooms: 90 +% .

7-007.04C4 Surgical areas must have heating and cooling systems that are capable of producing room temperatures at a range between 68 and 73

degrees Fahrenheit and humidity at a range between 30 and 60% relative humidity.

7-007.04C5 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

7-007.04C6 Floors in operating, procedure, and other locations subject to wet cleaning methods or body fluids must not have openings to the heating and cooling system.

7-007.04D Ventilation System: All facilities must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patients and employees.

7-007.04D1 Existing and new facilities must have adequate ventilation.

7-007.04D2 New construction must provide mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens, and similar rooms at ten air changes per hour.

7-007.04D3 New construction must provide mechanical ventilation system(s) capable of providing air changes per hour (hereafter ACH) as follows:

- | | | |
|----|--|-------------|
| 1. | Care and treatment areas: | 5 ACH; |
| 2. | Procedure and respiratory isolation areas: | 15 ACH; and |
| 3. | Operating rooms: | 20 ACH. |

7-007.04E Electrical System: The facility must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

7-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

7-007.04E2 All facilities must provide minimum illumination levels as follows:

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|-----|---------------------------------|-----------------------|
| 1. | General purpose areas: | 5 foot candles; |
| 2. | General corridors: | 10 foot candles; |
| 3. | Personal care and dining areas: | 20 foot candles; |
| 4. | Reading and activity areas: | 30 foot candles; |
| 5. | Food preparation areas: | 40 foot candles; |
| 6. | Hazardous work surfaces: | 50 foot candles; |
| 7. | Care and treatment locations: | 70 foot candles; |
| 8. | Examination task lighting: | 100 foot candles; |
| 9. | Procedure task lighting: | 200 foot candles; and |
| 10. | Surgery task lighting: | 1000 foot candles. |

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

7-007.04F Essential Power System: Facilities must have an emergency power generator for all care and treatment locations which involve general anesthetics or electrical life support equipment, and in emergency procedure and treatment rooms.

7-007.04F1 Existing and new facilities must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, and nurse call systems.

7-007.04F2 New construction must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, ventilation and heating systems, and nurse call systems.

7-007.04F3 Facilities with electrical life support equipment must maintain essential power systems and must have on-site fuel source. The minimum fuel source capacity must allow for non-interrupted system operation.

7-007.04G Call Systems: Call system(s) must be operable from patient procedure and operating rooms, recovery bed, and toilet areas. The system must transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

7-007.04G1 In new construction, the call system must have a dedicated emergency call device which allows activation by a patient from treatment rooms and cubicles, and toilet and bathing fixtures.

7-007.04G2 In new construction, in locations where patients are unable to activate the call, a dedicated staff assist call device must promptly summon other staff for assistance.

7-007.04G3 Existing health clinics, except ambulatory surgical centers, that do not have a nurse call system are not required to provide a nurse call system.

7-007.04H Medical Gas System: The facility must safely provide medical gas and vacuum by means of portable equipment or building systems as required by patients receiving care and treatment.

7-007.04H1 The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems must comply with the requirements of 153 NAC 1, Nebraska State Fire Code Regulations.

7-007.04H2 The facility must identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for patient care and treatment. The facility must document such approvals for review and reference.

7-007.05 Waivers: The Department may waive any provision of 175 NAC 7 relating to construction or physical plant requirements of a health clinic upon proof by the licensee satisfactory to the Department (a) that such waiver would not unduly jeopardize the health, safety, or welfare of the persons served by the facility, (b) that such provision would create an unreasonable hardship for the facility, and (c) that such waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

7-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in or served by the facility resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

7-007.05B Waiver Terms and Conditions: Any such waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a patient remain in effect as long as required by the patient;
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit a facility time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 7. An applicant for a waiver may construct a request for a waiver form or obtain a form from the Department.

7-007.05C Denial of Waiver: If the Department denies a health clinic's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

7-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

7-008.01 Grounds for Denial, Refusal to Renew or Disciplinary Action:

7-008.01A The Department may deny or refuse to renew a health clinic license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 7-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 7-008.01B.

7-008.01B The Department may take disciplinary action against a health clinic license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act, or 175 NAC 7;
2. Committing or permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a health clinic patient or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the health clinic;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the health clinic for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of such departments;
6. Discrimination or retaliation against a health clinic patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a health clinic patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the health clinic for the purposes of investigation

- necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Box Drug Act;
 10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
 11. Violation of the Medication Aide Act; or
 12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

7-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action:

7-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

7-008.02B The denial, refusal to renew, or disciplinary action will become final 15 days after the mailing of the notice unless the applicant or licensee, within such 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

7-008.02C Informal Conference

7-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

7-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

7-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

7-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing within five working days after receipt of the statement.

7-008.02D Administrative Hearing

7-008.02D1 When an applicant or a licensee contests the notice and request a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

7-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within such 30-day period, appeals the decision.

7-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

7-008.03 Types of Disciplinary Action

7-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license of a health clinic:

1. A fine not to exceed \$10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the facility or service may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the facility or service may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

7-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;

2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the health clinic in identifying or correcting the violation;
5. Any previous violations committed by the health clinic; and
6. The financial benefit to the facility of committing or continuing the violation.

7-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 7-008.03A.

7-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that patients of the health clinic are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the health clinic license, effective when the order is served upon the health clinic. If the licensee is not involved in the daily operation of the health clinic, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of patients; or
3. Order the temporary closure of the health clinic pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

7-008.03D1 The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

7-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

7-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

7-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

7-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

7-008.04A Reinstatement at the End of Probation or Suspension

7-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

7-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 7-003.02;
2. Payment of the renewal fee as specified in 175 NAC 7-004.09; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 7-005, that the health clinic is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 7-006 and 7-007.

7-008.04B Reinstatement Prior to Completion of Probation or Suspension

7-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:
 - a. The reasons why the license should be reinstated prior to the probation completion date; and
 - b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
2. Successfully complete any inspection that the Department determines necessary.

7-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
 - a. The reasons why the license should be reinstated prior to the suspension completion date; and
 - b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension.
2. Submit a written renewal application to the Department as specified in 175 NAC 7-003.02;
3. Pay the renewal fee as specified in 175 NAC 7-004.09; and
4. Successfully complete an inspection.

7-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

7-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

7-008.04C Re-Licensure After Revocation: A health clinic license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

7-008.04C1 A health clinic seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 7-003.01.

7-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 7-003.01.

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NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

HC
175 NAC 7

ATTACHMENTS

42 CFR 416.1 to 416.200
(Ambulatory Surgical Centers)

and

42 CFR 405.2100 to 405.2163
(Hemodialysis Services)

10-1-05 Edition of the
Code of Federal Regulations

(b) *Physician fee schedule.* (1) Services furnished by a resident in a nonprovider setting are covered as physician services and payable under the physician fee schedule if the following requirements are met:

(i) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry in the State in which the service is performed.

(ii) The time spent in patient care activities in the nonprovider setting is not included in a teaching hospital's full-time equivalency resident count for the purpose of direct GME payments.

(2) Payment may be made regardless of whether a resident is functioning within the scope of his or her GME program in the nonprovider setting.

(3) If fee schedule payment is made for the resident's services in a nonprovider setting, payment must not be made for the services of a teaching physician.

(4) The carrier must apply the physician fee schedule payment rules set forth in subpart A of part 414 of this chapter to payments for services furnished by a resident in a nonprovider setting.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 13, 2005]

§ 415.208 Services of moonlighting residents.

(a) *Definition.* For purposes of this section, the term *services of moonlighting residents* refers to services that licensed residents perform that are outside the scope of an approved GME program.

(b) *Services in GME program hospitals.*

(1) The services of residents to inpatients of hospitals in which the residents have their approved GME program are not covered as physician services and are payable under §§ 413.75 through 413.83 regarding direct GME payments.

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if all of the following criteria are met:

(i) The services are identifiable physician services and meet the conditions for payment of physician services to beneficiaries in providers in § 415.102(a).

(ii) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed.

(iii) The services performed can be separately identified from those services that are required as part of the approved GME program.

(3) If the criteria specified in paragraph (b)(2) of this section are met, the services of the moonlighting resident are considered to have been furnished by the individual in his or her capacity as a physician, rather than in the capacity of a resident. The carrier must review the contracts and agreements for these services to ensure compliance with the criteria specified in paragraph (b)(2) of this section.

(4) No payment is made for services of a "teaching physician" associated with moonlighting services, and the time spent furnishing these services is not included in the teaching hospital's full-time equivalency count for the indirect GME payment (§ 412.105 of this chapter) and for the direct GME payment (§§ 413.75 through 413.83 of this chapter).

(c) *Other settings.* Moonlighting services of a licensed resident in an approved GME program furnished outside the scope of that program in a hospital or other setting that does not participate in the approved GME program are payable under the physician fee schedule as set forth in § 415.206(b)(1).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 13, 2005]

PART 416—AMBULATORY SURGICAL SERVICES

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416.2	Definitions.

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§416.1

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- 416.195 A request to review.
- 416.200 Application of the payment adjustment.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for

Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.

(3) Section 1833(i)(2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified in §416.65 and are published by CMS in the **FEDERAL REGISTER**.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

Subpart B—General Conditions and Requirements

§416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

- (a) Meet the definition in §416.2; and
- (b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

§416.26 Qualifying for an agreement.

(a) *Deemed compliance.* CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) *Acceptance by CMS.* If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

[56 FR 8843, Mar. 1, 1991]

§416.30 Terms of agreement with CMS.

As part of the agreement under §416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) *Limitation on charges to beneficiaries.*¹ The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with §410.165 of this chapter.

(c) *Refunds to beneficiaries.* (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

¹ For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(d) *Furnishing information.* The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§416.120-416.130 in the form and manner that CMS requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under §424.55 of this chapter of the right to receive payment under Medicare Part B and payment under §424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hospital.* In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC, without the option of converting to or being paid as a hospital outpatient department, unless CMS determines there is good cause to do otherwise.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hospital's cost report.

(g) *Additional provisions.* The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 56 FR 8844, Mar. 1, 1991]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC—(1) Notice to CMS.* An ASC that wishes to terminate its agreement must send CMS written notice of its intent.

(2) *Date of termination.* The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it deter-

mines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Voluntary termination.* If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by CMS—(1) Cause for termination.* CMS may terminate an agreement if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under §416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination.* CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the ASC.* An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment is not available for ASC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by CMS.* When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 23454, June 12, 1987; 56 FR 8844, Mar. 1, 1991; 61 FR 40347, Aug. 2, 1996]

Subpart C—Specific Conditions for Coverage

§416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. *Standard: Hospitalization.* The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, non-participating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 23041, June 17, 1986]

§416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

- (1) A qualified anesthesiologist; or
- (2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.60(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(d) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001.]

§416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of

care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§ 416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish

notice in the FEDERAL REGISTER to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(i) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single

smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code*;

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

- (1) Emergency call system.
- (2) Oxygen.
- (3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.
- (4) Cardiac defibrillator.
- (5) Cardiac monitoring equipment.
- (6) Tracheostomy set.
- (7) Laryngoscopes and endotracheal tubes.
- (8) Suction equipment.
- (9) Emergency medical equipment and supplies specified by the medical staff.

(d) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005]

§416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) *Standard: Other practitioners.* If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(b) [Reserved]

§416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

- (1) Patient identification.
- (2) Significant medical history and results of physical examination.
- (3) Pre-operative diagnostic studies (entered before surgery), if performed.
- (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.
- (5) Any allergies and abnormal drug reactions.
- (6) Entries related to anesthesia administration.
- (7) Documentation of properly executed informed patient consent.
- (8) Discharge diagnosis.

§416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§416.49 Condition for coverage—Laboratory and radiologic services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare approved facility to meet the needs of patients.

[57 FR 7135, Feb. 28, 1992]

Subpart D—Scope of Benefits

§416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in §416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physi-

cian, are covered as physician services under part 410 of this chapter.

[56 FR 8844, Mar. 1, 1991]

§416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(8) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

[56 FR 8844, Mar. 1, 1991, as amended at 57 FR 33899, July 31, 1992]

§416.65 Covered surgical procedures.

Covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under § 405.310 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the **FEDERAL REGISTER** a list of covered surgical procedures and revisions as appropriate.

§ 416.75 Performance of listed surgical procedures on an inpatient hospital basis.

The inclusion of any procedure as a covered surgical procedure under § 416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

Subpart E—Payment for Facility Services

§ 416.120 Basis for payment.

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment is in accordance with part 413 of this chapter.

(b) [Reserved]

(c) *ASC—(1) General rule.* Payment is based on a prospectively determined

rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in § 416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in § 410.152 (a) and (i) of this chapter.

[56 FR 8844, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 416.125 ASC facility services payment rate.

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had been performed on an inpatient basis in a hospital.

[56 FR 8844, Mar. 1, 1991]

§ 416.130 Publication of revised payment methodologies.

Whenever CMS proposes to revise the payment rate for ASCs, CMS publishes a notice in the **FEDERAL REGISTER** describing the revision. The notice also explains the basis on which the rates

§416.140

were established. After reviewing public comments, CMS publishes a notice establishing the rates authorized by this section. In setting these rates, CMS may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8844, Mar. 1, 1991]

§416.140 Surveys.

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, CMS conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

42 CFR Ch. IV (10-1-05 Edition)

§416.150 Beneficiary appeals.

A beneficiary (or ASC as his or her assignee) may request a hearing by a carrier (subject to the limitations and conditions set forth in part 405, subpart H of this chapter) if the beneficiary or the ASC—

(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

SOURCE: 64 FR 32205, June 16, 1999, unless otherwise noted.

§416.180 Definitions.

As used in this subpart, the following definitions apply:

Class of new technology intraocular lenses (IOLs) means all of the IOLs, collectively, that CMS determines meet the definition of "new technology IOL" under the provisions of this subpart.

Interested party means any individual, partnership, corporation, association, society, scientific or academic establishment, professional or trade organization, or any other legal entity.

New technology IOL means an IOL that CMS determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

New technology subset means a group of IOLs that CMS determines meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of

a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.

§416.185 Payment review process.

(a) CMS publishes a **FEDERAL REGISTER** notice announcing the deadline and requirements for submitting a request for CMS to review payment for an IOL.

(b) CMS receives a request to review the appropriateness of the payment amount for an IOL.

(c) CMS compiles a list of the requests it receives and identifies the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(d) CMS publishes the list of requests in a **FEDERAL REGISTER** notice with comment period, giving the public 30 days to comment on the IOLs for which review was requested.

(e) CMS reviews the information submitted with the request to review, any timely public comments that are submitted regarding the list of IOLs published in the **FEDERAL REGISTER**, and any other timely information that CMS deems relevant to decide whether to provide a payment adjustment as specified in §416.200. CMS makes a determination of whether the IOL meets the definition of a new technology IOL in §416.180.

(f) If CMS determines that a lens is a new technology IOL, CMS establishes a payment adjustment as follows:

(1) Before July 16, 2002—\$50.

(2) After July 16, 2002—\$50 or the amount announced through proposed and final rulemaking in connection with ambulatory surgical center services.

(g) CMS designates a predominant characteristic of a new technology IOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish a specific subset of new technology within the "class of new technology IOLs."

(h) Within 90 days of the end of the comment period following the **FEDERAL**

REGISTER notice identified in paragraph (d) of this section, CMS publishes in the **FEDERAL REGISTER** its determinations with regard to IOLs that it has determined are "new technology" lenses that qualify for a payment adjustment.

(i) Payment adjustments are effective beginning 30 days after the publication of CMS's determinations in the **FEDERAL REGISTER**.

§416.190 Who may request a review.

Any party who is able to furnish the information required in §416.195 may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in §416.180.

§416.195 A request to review.

(a) *Content of a request.* The request must include all of the following information:

(1) The name of the manufacturer, the model number, and the trade name of the IOL.

(2) A copy of the FDA's summary of the IOL's safety and effectiveness.

(3) A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.

(4) A copy of the IOL's original FDA approval notification.

(5) Reports of modifications made after the original FDA approval.

(6) Other information that CMS finds necessary for identification of the IOL.

(b) *Confidential information.* To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, CMS maintains the confidentiality of the information and protects it from disclosure not otherwise authorized or required by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905).

§416.200 Application of the payment adjustment.

(a) CMS recognizes the IOL(s) that define a new technology subset for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years effective from the date that CMS recognizes the first new technology IOL for a payment adjustment.

(b) Any IOL that CMS subsequently recognizes as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with CMS's recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of CMS's initial recognition of a new technology subset, payment adjustments cease for all IOLs that CMS designates as belonging to that subset and payment reverts to the standard payment rate set under section 1833(i)(2)(A)(iii) of the Act for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to the class of new technology IOLs must submit claims using specific billing codes to receive the new technology IOL payment adjustment.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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if the reopening action was undertaken after May 27, 1972 (the effective date of regulations which, prior to the publication of this subpart R, governed the reopening of such determinations).

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 50110, Aug. 1, 2002]

§ 405.1887 Notice of reopening.

(a) All parties to any reopening described above shall be given written notice of the reopening. When such reopening results in any revision in the prior decision notice of said revision or revisions will be mailed to the parties with a complete explanation of the basis for the revision or revisions. Notices of reopenings by the Board shall also be sent to the Secretary.

(b) In any such reopening, the parties to the prior decision shall be allowed a reasonable period of time in which to present any additional evidence or argument in support of their position.

§ 405.1889 Effect of a revision.

Where a revision is made in a determination or decision on the amount of program reimbursement after such determination or decision has been reopened as provided in § 405.1885, such revision shall be considered a separate and distinct determination or decision to which the provisions of §§ 405.1811, 405.1835, 405.1875 and 405.1877 are applicable. (See § 405.1801(c) for applicable effective dates.)

Subparts S-T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b-8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 23511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have

in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in § 405.2101, and general definitions are contained in § 405.2102. The provisions of §§ 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§ 405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of "ESRD service"). Such facilities are:

(a) **Renal Transplantation Center.** A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(b) **Renal dialysis center.** A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis

furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) **Renal dialysis facility.** A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) **Self-dialysis unit.** A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) **Special purpose renal dialysis facility.** A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) **Transplantation service.** A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) **Dialysis service—(1) Inpatient dialysis.** Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) **Outpatient dialysis.** Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) **Staff-assisted dialysis.** Dialysis performed by the staff of the center or facility.

(ii) **Self-dialysis.** Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) **Home dialysis.** Dialysis performed by an appropriately trained patient at home.

(c) **Self-dialysis and home dialysis training.** A program that trains ESRD patients to perform self-dialysis or

home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through "agreements" or "arrangements").

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (MCE). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of *Organ procurement organization* in § 485.302 of this chapter.)

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) **Chief executive officer.** A person who:

(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) **Dietitian.** A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) **Medical record practitioner.** A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American

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Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.* A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) *Social worker.* A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies

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under paragraph (f)(1) of this definition.

(g) *Transplantation surgeon.* A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

[41 FR 23511, June 3, 1976. Redesignated at 42 FR 53826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6047, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990]

§ 405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation

and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.
(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;
(ii) Transplants; and
(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to pre-

pare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§ 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§ 405.2120 Minimum utilization rates: general.

Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) authorizes the Secretary to limit payment for ESRD care to those facilities that meet the requirements that the Secretary may prescribe, including minimum utilization rates for covered transplantations. The minimum utilization rates, which are explained and specified in §§ 405.2121 through 405.2130, may be changed from time to time in accordance with program experience. Changes will be published as amendments to these regulations.

[50 FR 23440, June 8, 1990]

§ 405.2121 Basis for determining minimum utilization rates.

In developing minimum utilization rates, the Secretary takes into account the performance of ESRD facilities, the

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availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

(a) Information on the geographic distribution of ESRD patients and facilities;

(b) Information on quality of care; and

(c) Information on operational and management efficiency.

[41 FR 22511, June 3, 1976, Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2122 Types and duration of classification according to utilization rates.

A renal transplantation center that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see § 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See § 405.2123 for reporting requirements; § 405.2124 for method of calculating rates; § 405.2130 for specific standards.)

(a) *Initial classification.* (1) A renal transplantation center that has not previously participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation.

(2) The renal transplantation center's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan.

(b) *Exception status.* (1) A renal transplantation center that does not meet the minimum utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if:

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(i) It meets all other conditions for coverage under this subpart;

(ii) It is unable to meet the minimum utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and

(iii) Its absence would adversely affect the achievement of ESRD program objectives.

(2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in § 405.2130(a), may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage as a renal transplantation center;

(ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (§ 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology;

(iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and

(iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.

[43 FR 48951, Oct. 19, 1978, as amended at 45 FR 58134, Sept. 2, 1980; 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2123 Reporting of utilization rates for classification.

Each hospital furnishing renal transplantation services must submit an annual report to CMS on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

[55 FR 23441, June 8, 1990]

§ 405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

§ 405.2130 Condition: Minimum utilization rates.

Unless a renal transplantation center is granted an exception under § 405.2122(b), the center must meet the following minimum utilization rate(s) for unconditional or conditional status:

(a) Unconditional status: 15 or more transplants performed annually.

(b) Conditional status: 7 to 14 transplants performed annually.

[55 FR 23441, June 8, 1990]

§ 405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.

A renal transplantation center or a renal dialysis center (§ 405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

§ 405.2132 [Reserved]

§ 405.2133 Condition: Furnishing data and information for ESRD program administration.

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not

disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

§ 405.2134 Condition: Participation in network activities.

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

§ 405.2135 Condition: Compliance with Federal, State and local laws and regulations.

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

§ 405.2136 Condition: Governing body and management.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer

who is responsible for the overall management of the facility.

(a) *Standard: disclosure of ownership.* The ESRD facility supplies full and complete information to the State survey agency (§ 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;

(2) Each officer and director of the corporation, if the facility is organized as a corporation; and

(3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) *Standard: Operational objectives.* The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that

may be performed, is readily available upon request to all concerned.

(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see § 405.2137).

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) *Standard: chief executive officer.* The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(1) Implementing the policies of the facility and coordinating the provision

of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, re delegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) *Standard: personnel policies and procedures.* The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local

professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing in-service training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) *Standard: use of outside resources.* If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service.

The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) *Standard: patient care policies.* The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physical plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) The provision of home dialysis support services, if offered (see § 405.2163(e)).

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physician director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physician-director provides medical guidance in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their non-working hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see § 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) *Standard: medical supervision and emergency coverage.* The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) *Standard: medical staff.* The governing body of the ESRD facility designates a qualified physician (see

§ 405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2137 Condition: Patient long-term program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.* There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to

treatment (see § 405.2161(b)(1) and § 405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see § 405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions

for visits to the home by qualified facility personnel to the extent appropriate. (See § 405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.

(vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.

(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.

[41 FR 22511, June 3, 1976, Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994]

§ 405.2138 Condition: Patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes

in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976, Redesignated at 42 FR 52836, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2139 Condition: Medical records.

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see § 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in § 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures;

and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information.* The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor.* A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) *Standard: retention and preservation of records.* Medical records are retained for a period of time not less than that determined by the State statute governing records retention or

statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 49952, Oct. 19, 1978; 52 FR 36934, Oct. 2, 1987]

§ 405.2140 Condition: Physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in "Hemodialysis Systems," second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's "Hemodialysis Systems," second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.¹ If any changes in "Hemodialysis Systems," second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and

¹The publication entitled "Hemodialysis Systems," second edition, 1992, is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244-1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

storage of reused items which conform to requirements for reuse in § 405.2150.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accommodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies.

(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see § 405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) *Standard contamination prevention.* The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see § 405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in § 405.2150.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in

equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or non-medical emergency occurs.

(Secs. 1102, 1871, 1881(b), Social Security Act; 42 U.S.C. 1302, 1395hh, 1395rr(b))

[41 FR 23511, June 3, 1976. Redesignated at 42 FR 53826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 45 FR 24839, Apr. 10, 1980; 52 FR 36934, Oct. 2, 1987; 60 FR 48043, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§ 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI ("Reuse of Hemodialyzers," second edition). Incorporation by reference of the AAMI's "Reuse of Hemodialyzers," second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.¹ If any changes in "Reuse of Hemodialyzers," second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) *Standard: Bloodlines.* If the ESRD facility reuses bloodlines, it must—

(1) Limit the reuse of bloodlines to the same patient;

(2) Not reuse bloodlines labeled for "single use only";

(3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and

(4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.

[52 FR 36935, Oct. 2, 1987, as amended at 55 FR 18335, May 2, 1990; 60 FR 48044, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§ 405.2160 Condition: Affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see § 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

¹The publication entitled "Reuse of Hemodialyzers," second edition, 1993, is available for inspection at the CMS Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244-1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

§ 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976, Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet

the needs of the patients, including those arising from medical and non-medical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis:

(1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;

(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.)

[41 FR 22511, June 3, 1976, Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services.*—(1) *Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in

accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) *Standard: Social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 496, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of—

(A) A physician who is responsible for all dialysis-related services and who

prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.* The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug "on hand" at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§ 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility

is consistent with the patient's long-term program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102) or a qualified physician-director (§ 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

§ 405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff;